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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,068	10/21/2005	Karl Kadler	17695-0002	2838

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EXAMINER

CARLSON, KAREN C

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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05/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/554,068

Applicant(s)

KADLER ET AL.

Examiner

Karen Cochrane Carlson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-104 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

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Claims 1-104 are currently pending and are subject to restriction. It is noted that many claims are improperly multiply dependent, and that many dependent claims recite elements not in the claims from which they depend from. See for example, Claims 29-31 and 34, for example, wherein Claim 1 is drawn to a modified pro α chain while claims 29 is drawn to the use of this, procollagen, polymer, matrix, or dressing of Claim 1. Claim 27 is drawn to a procollagen molecule, but Claim 34 is drawn to the use of collagen matrix, artificial skin, and body implants. Upon election, Applicants may wish to amend their claims to reduce the number of 112, 2nd paragraph rejections that is foreseen.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, 12-17, 19-21, 23-31, 34, 38-53, 55- 62, 63(NO: 9, 13)-99, drawn to a pro α chain comprising a triple helical domain and laminin, classified in class 530, subclass 350.
- II. Claims 1-4, 11-15, 18, 19, 23-31, 34, 50, 55, 57-59, 61, 63 (NO: 26)-67, 69-78, 80-89, 91-99, drawn a pro α chain comprising a triple helical domain and secretory leukocyte protease inhibitor, classified in class 530, subclass 350.
- III. Claims 32, 34, 103, drawn to artificial skin comprising pro α chain comprising a triple helical domain and laminin, classified in class 623.
- IV. Claims 32, 34, 103, drawn to artificial skin comprising pro α chain comprising a triple helical domain and secretory leukocyte protease inhibitor, classified in class 623.
- V. Claims 33, 34, 104, drawn to artificial skin comprising pro α chain comprising a triple helical domain and laminin, classified in class 623.

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- VI. Claims 33, 34, 104, drawn to artificial skin comprising pro α chain comprising a triple helical domain and secretory leukocyte protease inhibitor, classified in class 623.
- VII. Claim 35-37, 100, 101, drawn to Gene Therapy delivery system for DNA encoding pro α chain comprising a triple helical domain and laminin, classified in class 514, subclass 44.
- VIII. Claim 35-37, 102, drawn to Gene Therapy delivery system for DNA encoding pro α chain comprising a triple helical domain and secretory leukocyte protease inhibitor, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I through VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different products that do not overlap in structure or in function.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

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specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse:

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER

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